REMARKS

The Applicant acknowledges the Examiner's detailed statement regarding Election/Restrictions. The Applicant has amended the claims in light of the previous restriction and retains the right to pursue all non-elected subject matter in subsequent applications.

ARGUMENTS

OBVIOUSNESS

Claims 11-15 and 17-21 were rejected under 35 U.S.C. §103(a) as obvious in light of Wei, et al. (1993). The Examiner has not established a *prima facia* case of obviousness as set forth by MPEP §2143.

The Applicant has provided a Declaration executed by Dr. Charles R. Stewart which states: 1) He is the sole inventor of the antimicrobial SPO1 peptides; 2) Use of SEQ ID NO: 8 as an antimicrobial agent was not obvious because data establishing that gp44 would not cause lysis, and therefore would be useful in avoiding a Jarish-Herxheimer reaction, were not published until 2004; and 3) The presentation by Sampath in May of 2002 was the Applicant's own invention and occurred less than 1 year prior to filing USSN 60/457,287 therefore Sampath, 2002 is removed as prior art.

Prior Art Does Not Teach "inhibiting bacterial infection ... in a mammal"

To establish *prima facia* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. (MPEP § 2143.03). The prior art does **not** describe "inhibiting bacterial infection ... in a mammal" by "identifying the presence of a bacteria in a mammal" and "administering to said mammal a protein ..." The Examiner states that it would be obvious to one of ordinary skill in the art to utilize the antimicrobial peptides identified in Wei as antibiotics for inhibiting bacterial infections **in a mammal**.

However, all compounds which are suitable for killing bacteria are not suitable for inhibiting infections in a mammal. In 2004 it was determined that GP44

(SEQ ID NO: 8) was one of the class of proteins that do not cause cell lysis (Sampath, 2004). These results indicated GP44 (SEQ ID NO: 8) was a candidate antimicrobial peptide for "inhibiting bacterial infection ... in a mammal." Thus it would not have been prima facia obvious to use GP44 (SEQ ID NO: 8) as an antimicrobial agent "in a mammal" without characterizing its effects on bacterial cell lysis.

Long-felt but unsolved need to control the Jarisch-Herxheimer reaction

Regardless of method of administration, GP44 (SEQ ID NO: 8) will not cause bacterial lysis. The specification states, "The anti-microbial genes and peptides described herein could solve this problem, because each of them kills ***without*** lysing the bacterial cell." (emphasis added). It has been established that the GP44 (SEQ ID NO: 8) does not cause bacterial cell lysis (Sampath, 2004). The presence of the protein, topical use of the protein, and pharmaceutical applications of the protein will not cause cell lysis. There was a long-felt need for antibiotics that cause bacterial cell death without lysis because this reduces the Jarisch-Herxheimer reaction. The use of GP44 (SEQ ID NO: 8) solves a long-felt need for alternative antibiotics which do not cause a Jarisch-Herxheimer reaction and therefore is not obvious.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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